

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/SE2005/000308	International filing date (day/month/year) 03.03.2005	Priority date (day/month/year) 05.03.2004
International Patent Classification (IPC) or both national classification and IPC A61C8/00, A61B17/86		
Applicant LUNDGREN, Dan		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523655 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Pypen, C Telephone No. +49 89 2399-2799
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,
 claims Nos. 6

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 6 are so unclear that no meaningful opinion could be formed (specify):
see separate sheet

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the whole application or for said claims Nos. 6

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/SE2005/000308

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	7
	No: Claims	1-5, 8-16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-5, 7-16
Industrial applicability (IA)	Yes: Claims	1-5, 7-16
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

- D1: GB-A-1 203 093 (EDELMAN AND LINKHOW) 26 August 1970
- D2: US-A-5 433 607 (SCHMID ET AL) 18 July 1995
- D3: US-A-4 531 916 (SCANTLEBURY ET AL) 30 July 1985
- D4: US-A-4 359 318 (GITTLEMAN ET AL) 16 November 1982

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 is not new in the sense of Article 33(2) PCT.
 - 1.1. The document D1 (page 2, lines 55-66, Fig. 8) discloses a bone anchoring element comprising a tubular implant (67) to be inserted into bone tissue for anchoring a prosthetic component located outside the bone (65), which is open at one end thereof intended to be inserted into the bone tissue while the other end intended to be directed towards externally of the bone tissue located portions is closed by a compact impermeable end wall portion with attachment for the prosthetic component on the outside thereof, a lumen extending from the open end through the total implant to the end wall portion (66) *so that the lumen after insertion of the implant into the bone tissue includes at least the entire portion of the implant which is intended to be anchored in the bone tissue*, whereby the implant has a compact impermeable side wall with a stop mark for defining an end position for the implant at insertion into the bone tissue, and that the lumen of the implant also includes a cavity in the end wall portion open towards the lumen *so that the lumen has such an extension that it after insertion of the implant into the bone also will be located above the bone level established around the implant.*
 - 1.2. The features placed in italic in claim 1 are features defining the implant as a function of its position in the bone, which is not part of the subject-matter as claimed in claim 1, instead of defining the implant by its technical features. Hence, the limitation of claim 1 therefore is not clear (Article 6 PCT).
Moreover, any implant known from the state of the art can be implanted into the bone so that both features claimed will be fulfilled.
 - 1.3. The subject-matter of claim 1 is also known from the documents D2 (Fig. 4B) and D3

(column 3, lines 42-49; column 4, lines 30-33; Fig. 2).

- 1.4. Hence the subject-matter of claim 1 is not new (Article 33(2) PCT).
2. The application does not meet the requirements of Article 6 PCT, because claims 2, 3, 6, 9, 10, 12-14 are not clear.
 - 2.1. It is not clear how a stop mark, having to indicate the depth of implantation of the implant in the bone, can be an inside shoulder (claim 2).
It is not clear either how an inside shoulder, being formed by the inside of the end wall portion can be visible (claim 3).
 - 2.2. The technical feature "synchronic macro or micro threads" (claim 6) is not common used term, and is not defined in the description. Also, claims 6 being dependant of claim 5, only existing outside *or* inside threads can be claimed.
 - 2.3. Claim 9 seems to contain all features of claim 1, and hence has the same subject-matter as claim 1.
 - 2.4. The additional features of claims 10, 12, 13, and 14 are dependent on the depth of implantation of the implant into the bone, which is not part of the subject-matter of these claims (see §1.2.).
3. Furthermore, the above-mentioned lack of clarity notwithstanding, dependent claims 2-5, 7-16 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.
 - 3.1. The document D1 (Fig. 1, 3, 8; page 2, lines 22-24, 64-67) discloses the additional technical features of the claims 2-5, 10-15.
 - 3.2. The document D2 (Fig. 4B; column 4, 52-65; column 11, lines 4-8) discloses the additional features of claims 2-4, 8, 10-14.

- 3.3. The additional technical features of the claims 2-4, 11, 13 are also disclosed in D3 (Fig. 2; column 1, lines 65-68; column 3, lines 42-49; column 4, lines 30-33).
- 3.4. The document D4 (column 6, lines 45-49) discloses the additional technical features of the claims 15-16.
- 3.5. The subject-matter of claim 9 being the same as of claim 1, it is known from the documents D1, D2 and D3 (see §1).
- 3.6. Hence the subject-matter of claims 2-5, 8-16 is not new (Article 33(2) PCT).
- 3.7. The use of a thread having a double entrance is a normal design procedure the skilled person would apply. Therefore, the subject-matter of claim 7 does not involve an inventive step (Article 33(3) PCT).
4. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.
The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
5. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).
If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.
The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT.
Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.